

**REMARKS**

Claims 1-22 were pending in the application. The Office Action dated November 30, 2007 (“Office Action”) objected to the oath/declaration as being defective for failing to comply with 37 C.F.R. § 1.63(b)(3). The Office Action objected to the specification for failing to provide a proper antecedent basis for the claimed subject matter. Claims 1-22 were objected to for certain informalities. The Office Action rejected claims 1-22 under 35 U.S.C. § 112, first paragraph, for failing to comply with the written description requirement. Claims 1-17 and 19-22 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the inventive subject matter. Claims 1, 2, 4-15, and 18-20 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,156,594 to Keith (“Keith”). Claims 3, 16, and 17 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Keith in view of U.S. Patent No. 6,309,379 to Willard et al. (“Willard”). Claims 21 and 22 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Keith in view of U.S. Patent No. 6,030,405 to Zarbatany et al. (“Zarbatany”).

By the present Response, claims 1, 5, 13, and 17-19 have been amended, and claims 3 and 16 have been cancelled. Claims 1, 2, 4-15, and 17-22 are now pending in the present application. Reconsideration of the previously rejected claims and favorable action is requested in light of the above amendments and the following remarks.

**Oath/Declaration Objection**

The Office Action objected to the oath/declaration for failing to comply with 37 C.F.R. § 1.63(b)(3), because it contains the phrase “which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations 1.56(a).” Applicant respectfully submits that, in view of a recent Notice issued by the PTO on January 22, 2008, entitled “Duty of Disclosure Language Set Forth in Oaths or Declarations Filed in Nonprovisional Patent Applications” (the “Notice”), the original declaration filed in the present application is not defective and thus a new declaration is not required. In the Notice, the PTO waived the express language requirement of 37 C.F.R. § 1.63(b)(3) for all pending applications

and issued patents where the oath or declaration was filed prior to June 1, 2008. (*See* Notice at page 2.) More specifically, the PTO explained that “[t]he express language of 37 CFR 1.63(b)(3) is waived only to the extent necessary such that an oath or declaration containing the ‘material to examination’ or ‘in accordance with § 1.56(a)’ language, or both, will be accepted as acknowledging the applicant’s duty to disclose information ‘material to patentability’ as defined in 37 CFR 1.56.” (Notice at page 2.)

Since the original declaration filed in the present application contains the language “material to the examination of this application in accordance with Title 37, Code of Federal Regulation, 1.56(a),” and was filed on July 24, 2003, the express language requirement of 37 C.F.R. § 1.63(b)(3) is waived with respect to the present application. Thus, the original declaration is not defective, and there is no requirement for Applicant to file a substitute declaration.

#### Specification Objection

The Office Action objected to the Specification for failing to provide proper antecedent basis for the claimed subject matter. Applicant submits that the claims, as currently amended, find proper support in the Specification. Therefore, Applicant respectfully requests that the objection be withdrawn.

#### Claim Objections

The Office Action objected to claims 1-22 for containing certain informalities. Claims 1, 18, and 19 have been amended to resolve these informalities. Therefore, Applicant respectfully requests that the objections be withdrawn.

#### Claim Rejections – 35 U.S.C. § 112, First Paragraph

The Office Action rejected claims 1-22 under 35 U.S.C. § 112, first paragraph, on the basis that the claims contain subject matter that was not described in the specification in a way that would reasonably convey to one of skill in the art that the inventor possessed the claimed

invention at the time the application was filed. Specifically, the claims were rejected because they contained references to the guide tube proximal end being “flute cut.” The claims have been amended so that they no longer refer to the term “flute cut.” Therefore, Applicant respectfully requests that the rejections be withdrawn.

Claim Rejections – 35 U.S.C. § 112, Second Paragraph

The Office Action rejected claims 1-17 and 19-22 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the inventive subject matter. Specifically, the Office Action asserted that the claim language “having a lateral aperture delimiting a main tube edge” was unclear. Also, the Office Action claimed that the claim language “flute cut being joined to at least a portion of the distal tube outer edge and at least a portion of the main tube edge defining a side port in the catheter structure” was unclear. The claim have been amended to obviate these concerns. Therefore, Applicant respectfully requests that the rejections be withdrawn.

Claim Rejections – 35 U.S.C. § 102(b)

The Office Action rejected claims 1, 2, 4-15 and 18-20 under 35 U.S.C. § 102(b), as being anticipated by Keith. Keith discloses an over-the-wire balloon dilatation catheter that has a stainless steel hypotube catheter shaft, an intermediate sleeve section bonded to the shaft, and a distal balloon section connected to the sleeve section.

To establish a prima facie case of anticipation under 35 U.S.C. § 102(b), the prior art reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. MPEP § 2131. Applicant respectfully submits that Keith does not anticipate claims 1, 2, 4-15 and 18-20.

As currently amended, claim 1 of the present application recites, in part, “[a] catheter structure comprising: a main tube having a proximal end and a distal end, said main tube distal end having a lateral opening; a distal tube having a proximal end and a distal end; and a guide tube having a proximal end and a distal end, . . . a portion of said guide tube adjacent to said

guide tube proximal end extending into said lateral opening of said main tube distal end, *said main tube having a part which is deflected and inclined towards the inside of said main tube, and a portion of said guide tube adjacent to said guide tube proximal end resting on the outside of said deflected and inclined part of said main tube.*" The Office Action admits that "Keith is silent on the proximal end of the guide tube resting on the outside of the inclined part of the main tube." For at least this reason, Keith fails to teach or suggest all the features of claim 1.

Independent claims 18 and 19 recite similar features to those described above, and are thus distinguishable over Keith for at least the same reason as claim 1. Dependent claims 2, 4-15, and 20 incorporate all the features of the independent claim from which they depend, and, therefore, are also distinguishable over Keith for at least the reason discussed above.

For the foregoing reasons, Applicant respectfully submits that claims 1, 2, 4-15 and 18-20 are allowable over Keith. Favorable reconsideration of the claims is requested, including removal of the rejections under 35 U.S.C. § 102(b).

Claim Rejections – 35 U.S.C. § 103(a)

The Office Action rejected claims 3, 16, and 17 under 35 U.S.C. § 103(a), as being unpatentable over Keith in view of Willard. Willard discloses an intravascular selection sheath that comprises a tubular body having proximal, intermediate, and distal sections, and a lumen extending therethrough. The portion of the lumen in the distal section can be occupied by only one of the other intravascular devices of the predetermined sizes at a given time.

To establish a prima facie case of obviousness, three criteria must be met. First, there must be some reason to modify the references or to combine the teachings of the references. Second, there must be some expectation of success. Third, the prior art references must disclose or suggest all of the claimed features. See MPEP § 2143; the May 3, 2007 letter from the PTO Deputy Commissioner for Patent Operations regarding *KSR Int'l Co. v. Teleflex, Inc.*

Applicant notes that, by the present Response, claim 1 has been amended to incorporate the features of claims 3 and 16. As discussed above, claim 1 recites, in part, "[a] catheter structure comprising: a main tube having a proximal end and a distal end, said main tube distal

end having a lateral opening; a distal tube having a proximal end and a distal end; and a guide tube having a proximal end and a distal end, . . . a portion of said guide tube adjacent to said guide tube proximal end extending into said lateral opening of said main tube distal end, *said main tube having a part which is deflected and inclined towards the inside of said main tube, and a portion of said guide tube adjacent to said guide tube proximal end resting on the outside of said deflected and inclined part of said main tube.*" Applicant respectfully submits that, like Keith, Willard does not teach a guide tube proximal end resting on the outside of a deflected and inclined part of a main tube, and thus it does not compensate for the deficiency in Keith with respect to claim 1.

Figure 1 of the present application clearly shows the guide tube (13) *resting* on the *outside* of the part of the main tube (11) that is deflected in towards the main tube – a feature that is expressly recited in claim 1. The Office Action contends that Figure 10 of Willard discloses this feature. However, Figure 10 of Willard merely shows a liner (102) *passing through* an opening (50), which happens to be located on an inclined part of a sheath (10). It is evident from Figure 10 of Willard that the liner (102) does not rest on the *outside* of the inclined part of the sheath (10). Applicant notes that this claimed feature is not trivial. As explained in the Specification, this particular feature of the present invention allows for a more robust catheter structure. (Specification at ¶ 18.) Therefore, Applicant respectfully submits that claim 1 is distinguishable over Keith in view of Willard.

Claim 17 depends directly from claim 1 and thus is distinguishable over Keith in view of Willard for at least the same reason as claim 1. Favorable reconsideration of the claims is requested, including removal of the rejections under 35 U.S.C. § 103(a).

Claim Rejections – 35 U.S.C. § 103(a)

The Office Action rejected claims 21 and 22 under 35 U.S.C. § 103(a), as being unpatentable over Kieth in view of Zarbatany. Zarbatany discloses a dilation catheter having a balloon inflation shaft with an inflation lumen into which a stiffening wire extends, and a guidewire shaft having a guide wire lumen adjacent to the balloon. The stiffening wire includes

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at least two stepped diameter reductions along its length to vary stiffness from a stiff proximal end, providing improved pushability to a less stiff distal end and providing improved trackability.

Claims 21 and 22 depend directly or indirectly from claim 19, and thus incorporate all the limitations of claim 19. As noted above, the Office Action admits that “Keith is silent on the proximal end of the guide tube resting on the outside of the inclined part of the main tube.” Zarbatany fails to compensate for that deficiency. Therefore, Applicant respectfully submits that claims 21 and 22 are distinguishable over Keith in view of Zarbatany. Favorable reconsideration of the claims is requested, including removal of the rejections under 35 U.S.C. § 103(a).

For the foregoing reasons, Applicant submits that all of the currently pending claims are in condition for allowance.

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**CONCLUSION**

In view of the foregoing, the Applicant submits that this application is in condition for allowance and such disposition is earnestly solicited. If the Examiner believes that the prosecution of this case might be advanced by discussing the application with the Applicant's representative, in person, or over the telephone, we would welcome the opportunity to do so.

EXCEPT for fees payable under 37 CFR §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application, including fees due under 37 CFR §1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to deposit account No. 50-1349. This paragraph is intended to be a constructive petition for extension of time in accordance with 37 CFR §1.136(a)(3).

Respectfully submitted,

**HOGAN & HARTSON LLP**

Dated: March 18, 2008

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